

201-15299

May 24, 2004

Michael O. Leavitt, Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Building (1101A)  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

Re: Comments on the HPV test plan for thiodipropionitrile

Dear Administrator Leavitt:

The following comments on the Thioesters Association test plan for thiodipropionitrile (CAS no. 111-97-7) are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health and environmental protection organizations have a combined membership of more than ten million Americans.

The Thioesters Association has carried out a thorough assessment of available information and has appropriately concluded that no further animal tests are needed. No additional repeated-dose and reproductive toxicity tests are needed because thiodipropionitrile is a closed-system intermediate (item 7 in the EPA's letter to manufacturers and importers, October 14, 1999, <http://www.epa.gov/chemrtk/ceoltr2.htm>). Further, the extremely low potential for any human exposure obviates the need for developmental toxicity tests.

It is unfortunate in the extreme that the HPV program does not allow for/require/encourage a strong exposure component. The Association states that the total number of workers employed in the manufacture and use of thiodipropionitrile in the USA is fewer than 50 (test plan, p. 13). In addition to its being a closed system intermediate, a number of precautions are in place to avoid employee exposure. It is therefore completely reasonable to avoid conducting a developmental toxicity test, and even more so if the employees are male.

The Association has rightly accepted the use of ECOSAR as an alternative to fish toxicity testing.

Lastly, the Thioesters Association plans to carry out a chromosomal aberration test (p. 9). It does not state whether this will be an *in vitro* or *in vivo* test, but EPA guidance states that genetic toxicity testing should be conducted *in vitro*. We recommend that the cells used in this test be human lymphocytes, or, if they are animal cells (e.g. Chinese hamster ovary cells), that they are be from a long-established and immortal culture, so as not to require the use of additional animals.

Sincerely,

Jessica Sandler  
Federal Agency Liaison



PEOPLE FOR THE ETHICAL  
TREATMENT OF ANIMALS

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